Eliminating Ferrous Contamination in Critical and Sterile Equipment Maintenance

By Brian Pekarsky

Executive Summary

Although the pharmaceutical industry today is a highly automated industry, key decisions are still made by individuals. What equipment you procure, which employees you hire and how well you train them are all important factors that will have a significant effect on achieving efficient production. In critical and sterile processing, even seemingly small decisions can affect productivity and compliance with regulatory standards. As a decision maker, your responsibilities are to identify all possible sources of contamination in your Cleanroom facility and maintain efficient production. Once a source of contamination is identified, you need to eliminate it at the lowest cost without compromising the integrity of the process. But, if it were as simple as that-- as identifying and eliminating contaminants-- anyone could do it. To "think outside the box", however, requires a new approach. To recognize the possibility of additional sources of contamination not previously identified requires progressive thinking and initiative. In the pages that follow, I will introduce a concept that will allow you to implement a simple, yet progressive Standard Operating Procedure for the maintenance and use of sterile processing equipment.

Introduction

The implementation of a simple procedural standard can increase product safety and production efficiency.

Sterile processing industries are unique compared to general industries and require a set of solutions to address their unique needs. As obvious as this may sound, you may be surprised to know how often this simple idea is overlooked and what efficiency is lost because of it. Sterile processing is not general industry. The procedures are different, the requirements and standards are different, and the expectations concerning the end product are different. In industries in which regulatory agencies such as the FDA oversee production and ensure the safety of the end product, you might expect the tools and equipment used would be different as well, held to strict industry-specific standards. But, with regard to tools used in the maintenance and installation of sterile processing line equipment, the industry as a whole is lagging behind the pace of the technological advances that define it in so many other aspects.

Historical overview: The "Stone Age" of Sterile Processing and the Technology of Tools

Modern technologies require modern solutions.

Historically, the progression of civilization has been measured by the types and complexity of its tools. From basic stone implements right up to the industrial age, tools serve as a benchmark of technological advancement. As modern technological advances in scientific research continually expand the possibilities of today's global pharmaceutical and biotech industries, the tools and machinery used in production facilities must also continually adapt to meet the changing requirements of progress. In many circumstances, that adaptation represents an increase in complexity, such as larger and more efficient industrial machinery designed to meet the high volume needs of rapidly increasing production demands. In other cases, that adaptation requires not an increase in complexity but a return to first principles with a new, forward-thinking approach.

Aseptic processing industries can be an ideal example of the successful application of the latter: an easy to implement, cost effective solution that addresses and solves an often overlooked but critical problem-- ferrous contamination of sterile process manufacturing from carbon steel hand tools.

The electroplated surfaces of carbon steel tools are subject to deterioration- a sure way to contaminate critical processes.

The application of electroplated surface coatings on general industrial hand tools is intended to provide the carbon steel with some level of corrosion resistance by acting as a barrier between the free iron on the tool surface and the environment, thereby reducing the level of oxidation. Although plated carbon steel tools can be effectively sterilized for acceptable use in sterile processing, each successive autoclave cycle actually deteriorates the plating, causing it to chip, flake, and peel.

Particulate generation from hand tools can be eliminated at the source by removing carbon steel tools from all sterile areas.

The danger of contamination from the particulate generated by repeated sterilization cycles of carbon steel tools can be considered a process risk on two fronts. In the first instance, perhaps the more obvious threat, it is the chrome plating itself. Tiny flakes and chips from the deteriorating chrome plating can easily introduce foreign matter into sterile processes in any number of ways including transference directly from the tool surface or bodily by the mechanic. In the second instance, and perhaps a more insidious threat, contamination of the Cleanroom or sterile environment is introduced when the exposed ferrous surface of a tool is used on the stainless steel surface of the equipment being serviced or against a stainless steel fastener. The contact of the two different materials during the course of normal use transfers iron particles from the carbon steel tool to the surface of the stainless steel fastener or equipment surface. The reaction between the exposed iron particles and oxygen over time in an environment with even low levels of humidity results in the formation of iron oxide. This poses an obvious threat to maintaining acceptable levels of airborne particulate.

As you can see, sterilization of maintenance tools is only part of the battle against contamination. The risk of ferrous transfer -- the transference of iron particles from carbon steel tools to a stainless steel surface-- insures that sterilization alone has little effect against the long-term integrity of critical equipment.

Do You Use Steritools?

Proper maintenance tools offer the innovative plant manager an opportunity to raise standards and achieve noticeable results.

Until recently, the same maintenance tools used by the auto mechanic in your local repair shop-- wrenches, pliers, sockets, etc., also represented the state of the art in critical process machinery maintenance, simply because there was no alternative. But although automobile maintenance is a specialized industry with many highly skilled, knowledgeable mechanics, you wouldn't allow your auto mechanic into your Cleanroom to work on your equipment without first providing him with the proper clothing and procedural training that your industry requires. The same should hold true for the tools you might expect him to bring along with him. Just because a wrench can be used to turn a nut doesn't mean it belongs in a Cleanroom. Proper maintenance tools for critical environments -- ones that eliminate the risk of ferrous contamination and particulate generation-- are an often overlooked but integral component of critical processing procedure. Implementing the use of these tools offer the innovative plant manager an opportunity to raise standards and achieve noticeable results.

Stainless steel has long been the standard for medical and dental instruments for a good reason. As the name would imply, it is designed to resist the oxidation that results from the migration of free iron to the surface in carbon steel. It achieves this mainly with the addition of chromium at 10% or more by weight. Other elements such as molybdenum, nickel, copper, titanium, carbon, aluminum, and others are also added for improved corrosion resistance, workability, and strength. But it is the chromium content that allows the formation of a thin, non-reactive chromium oxide layer on the surface. This passive, protective layer is key: it prevents the interaction of free iron with oxygen and thus prevents oxidation. Because this protection is achieved without the addition of surface applied plating, stainless instruments can be effectively sterilized and cleaned without concern for deterioration. In a sterile operating theater or even in a dentist's office, this important benefit is obvious. But what about other critical environments which require monitored levels of contamination and airborne particulate? Pharmaceutical production, Biotech research and development, High Purity Vacuum chambers, Semiconductor Cleanrooms, Nuclear facilities, and Food production are all examples of high tech industries that require either sterilization or high levels of cleanliness.

The logical consequence of applying the same technology used for medical instruments to tools used in other critical industries results in the evolution of an entirely new, purpose-built class of instruments: stainless steel hand tools. This brief associative description represents a dramatic shift taking place in critical processing industries.

stainless = sterile
stainless tools = sterile tools
The result: **Steritools™**

The Steritools™ concept: purpose-built hand tools for critical environments.

Steritools™, or hand tools manufactured specifically for use in critical areas, present no risk of ferrous or particulate contamination. Borrowing the basic philosophical principles of their design from their medical roots, Steritools™ are intended to "first, do no harm". They are engineered to have no negative impact on critical environments over their lifetime of use under conditions of frequent and repeated sterilization.

Case study: The Hex Key. The Evolution of the Revolution

The hex key, or wrench, also widely known by the trade name Allen key, is one of the simplest hand tools there is. A hexagonal shaft of metal, cut to a certain length and bent ninety degrees to form an "L". Used to drive hex head fasteners of all shapes and sizes in a virtually unlimited number of industrial applications, every maintenance mechanic has a few sets in his toolkit.

You wouldn't think that designing a Steritool™ version would be any more complicated than cutting and bending a bar of stainless steel. But which alloy to use? As mentioned earlier, it is the addition to iron of several elements including chromium that gives stainless steel its corrosion resistant properties. There

Factors considered in the selection of an appropriate alloy for Steritools™ include corrosion resistance, tensile strength, and hardness.

are thousands of stainless alloy combinations possible, though of course in practice there are a few dozen in common use. Among those, only a few are suitable for the construction of many of the most commonly used hand held tools. Corrosion resistance alone is not the only factor taken into consideration when selecting a stainless alloy for the manufacture of steritools. Hardness and tensile strength also play an important role in determining the usefulness of a tool. Small components that will come under high torque must be able to withstand the force without deforming. The same holds true for cutting tools and the teeth in the jaws of pliers.

Those who are even marginally familiar with the names of one or two different stainless alloys in the United States usually are familiar with "316". This common stainless alloy containing 16-18% chromium and 10-14% nickel is well known for its excellent corrosion resistance and is used in a wide variety of applications including industrial and laboratory equipment, food service preparation areas, sinks, kitchen utensils and appliances. For many people, the corrosion resistant properties of this alloy would seem to make it an ideal alloy for a Steritool™ hex key. But, 316 is a low carbon, non-thermally hardenable alloy and therefore is not capable of achieving the hardness level required for high torque applications such as those which are normal in the everyday use of hex keys. On the Rockwell C hardness scale, 316 can achieve only a 28. By comparison, common industrial carbon steel can achieve a HRC (hardness Rockwell C) of 59.

Tools which as subject to high torque, such as small hex keys, require a high level of hardness. Until recently, this has come at the sacrifice of corrosion resistance.

Higher carbon content in "400 series" stainless steels offers a more appropriate level of hardness, but at the same time the increase in carbon (from approx 0.08% in 316 to .15% in 420, a commonly used alloy) lowers the alloy's resistance to corrosion. To counteract this, other alloys such as chromium are added in increased amounts. 400 series stainless steels are commonly used in dental and surgical instruments and in many steritools which require harder surfaces or greater tensile strength. The small serrations in the jaws of common slip joint pliers, for example, would likely wear too easily under normal use if it were manufactured from 316.

Metallurgists are well aware of the necessary compromises between corrosion resistance and hardness that exist in producing a stainless steel alloy. They understand better than anyone that no single alloy will be suitable for all purposes. Developments in research and technology, however, allow them to continually advance the art and science of stainless steel production and in turn reduce the limitations of compromise. Traditional p*recipitation hardening* (PH) alloys, such as 17-4PH, have successfully managed to bridge that gap for many applications. By maintaining a low carbon content, PH series alloys retain superb corrosion resistant properties approaching that of austenitic “300” series stainless alloys. With a HRC of 44, 17-4PH is perfectly suitable for a wide range of hand-driven Steritools including sockets, nut drivers, ratchets and drive accessories. Our testing has shown good compatibility with hex keys as well, though bar diameters of .187 and smaller revealed an unacceptable tendency toward deformation. This led to the development of the next generation of PH stainless alloys able to achieve greater hardness.

What’s in a name?

Don’t judge a book by its cover- or an alloy by it name.

Sometimes, nothing more than confusion. Advances in manufacturing and technology have led Carpenter Technologies, a manufacturer of specialty alloys, to first produce Custom 455® stainless and shortly thereafter, Custom 465® stainless. These proprietary, precipitation hardening, low carbon alloys can achieve a greater hardness with excellent tensile strength without sacrificing corrosion resistance. After extensive testing, Custom 465®, with a tensile strength of 260ksi and able to achieve a HRC of 54, was quickly adopted as the alloy of choice for all Steritool™ hex keys. Custom 465® has proven its worthiness over time, with excellent results in hex keys of even the smallest diameter. It is somewhat unfortunate that the numerical value assigned to its name leads many people to initially associate the alloy with high carbon “400” series alloys such as 420. However, cases of metallurgical “mistaken identity” are quickly overlooked as the alloy has found overwhelming acceptance as an integral part of the Steritool™ line in critical environment use.

Compliance, Cost Savings, and Cleanliness

Initiating a simple Standard Operation Procedure with regard to the implementation of steritools for all critical maintenance applications is the most effective way to achieve results in all three areas: compliance with regulatory standards, production cost savings, and maintaining hand tool cleanliness in critical areas.

Steritools™ offer an effortless, risk avoidant solution to hand tool contamination in sterile and critical facilities worldwide.

As already stated, general industrial carbon steel tools are unsuitable in every way for critical applications. Sterilizing carbon steel tools causes rapid deterioration of applied surface plating, drastically increasing the risk of process contamination from chrome and iron particulate.

Production engineers, maintenance mechanics and quality control personnel understand these risks well, and have had to compensate for the potential risk of contamination by frequently replacing carbon tools. As soon as the slightest sign of deterioration shows itself on a tool, the tool needs to be discarded and replaced with a new one.

This frequent replacement of tools has certainly led more than few forward-thinking equipment operators and maintainers to wonder as they discarded yet another $15 adjustable wrench, ***at what other point in the manufacturing of FDA regulated products would you use the same equipment that your auto mechanic would use to fix your car?***

Clearly, this is a waste of money when you factor in the variables of cost per tool, frequency of replacement, and number of facilities-- in many cases worldwide-- which require the use of the tool for a same or similar procedure. The cost savings is easily realized by a few simple substitutions in the equation below, using the $15 adjustable carbon steel wrench as an example.

(cost per tool) x (frequency of replacement) x (number of facilities worldwide).

Steritool™ Green: Cleanrooms are not the only environment *suffering under carbon steel tools. Discarded tools- on a global scale- end up in landfills and contribute to waste management problems.*

Let's assume that an average chrome plated wrench is put through an autoclave cycle once per day, five days per week, and that it withstands twenty such cycles before showing obvious deterioration. Even with this generous assumption of quality, it is easy to see that the useful life of the wrench will be approximately one month, and by the end of one year the total replacement cost of that one wrench will have been approximately $180.00. In contrast, with a stainless steel wrench designed for autoclaving which costs approximately $125.00, the return on investment will be realized in the first nine months **and the source of potential contamination will have been removed from the process**. The wrench will not have to be discarded, further maximizing your return for years to come. Considering these simple numbers-- factoring in the average quantity of tools used over time and the number of manufacturing facilities in a typical organization-- the cost savings expand exponentially. It is easy to see that the implementation of a simple procedural standard-- the replacement of carbon steel maintenance tools with steritools -- can have an enormous positive effect on production safety, regulatory compliance, and efficiency.

The Steritool™ Standard Operating Procedure:

Benefits at a glance

	Steritools™	Carbon Steel Tools
Risk of Process Contamination	**Low**	High
Particulate Generation	**Homogenous material- no plating to peel or chip**	Chrome Plating- chips or flakes can generate particulate
Sterility	**Designed specifically for routine sterilization through thousands of cycles**	Can only be effectively sterilized for approximately ten cycles before deterioration begins
Ferrous Contamination	**Pure chromium oxide surface creates passive (non-reactive) layer with no iron contamination**	Made from carbon steel with chrome plating. Ferrous surface introduces high risk of ferrous contamination
Cost	**Long life of the tools eliminates the need for replacement and quickly maximizes return on investment**	Necessity of frequent replacement results in high cost over time
Design	**Designed and specified for critical environment applications**	Designed for general industrial use. Not intended for sterilization
Critical Environment	**No negative impact on critical environments**	Introduces particulate and iron contamination

In 1993, Steritool Inc revolutionized the way critical and sterile processing industries manage maintenance tasks by introducing a line of industry-appropriate stainless steel maintenance tools. Today, with over 700 catalog line items, Steritool™ is the world leader in stainless steel hand tool technology.
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